SEP 1 5 2008

enpath medical

510(K) Summary

510(k) Number: K081394

Date Prepared

August 19, 2008

Submitter Information

Submitter's Name/ Address:	Enpath Medical 2300 Berkshire Lane North Minneapolis, MN 55441
Establishment Registration:	2183787
Contact Person:	Shannon Springer Principal Regulatory Affairs Associate sspringer@enpathmed.com (763) 951-8244 (phone) (763) 559-0148 (fax)

Device Information

Trade Name:	PTFE Peelable Introducer
Classification Name:	Introducer, Catheter
Product Code:	DYB
Regulation:	Class II, 21 CFR 870.1340
Panel:	Cardiovascular

Performance Standards

No performance standards applicable to this product have been developed under Section 514 of the Act.

Predicate Device

Enpath Medical, Inc. Percutaneous Introducer *(K000824)*

Device Description

The Enpath Medical PTFE Peelable Introducer kit consists of a disposable needle, a disposable syringe, a guidewire, and a peelable introducer set consisting of a dilator and sheath with integrated proximal handles. The Introducer is available in various lengths in 3.5F through 7F (micro) and 7F through 16.5F (macro). The

dilator is designed to be delivered over a 0.018" guidewire (micro) up to a 0.038" guidewire (macro).

The dilator and hub is constructed of high density polyethylene. The outer sheath and handle is constructed of PTFE and TPX. The inner dilator and outer sheath are radiopaque so that they are visible under fluoroscopy. The hub of the dilator has a spin lock design that connects to the luer of the sheath when rotated.

The Percutaneous Introducer sheath has a "tear-away" feature which allows the user to remove the sheath without removing the inserted catheter or pacing lead. The kit is packaged in a tray and placed into a poly-Tyvek pouch and sealed.

Indications for Use

Peelable Introducer is intended for use in the percutaneous insertion of pacing leads or catheters in the venous system.

Summary of Non-Clinical Testing

Performance Testing: The performance testing for this device included testing to verify that the device continues to functions in a safe and effective manner. The performance testing included the device specifications, functional and dimensional testing of the PTFE Peelable Introducer and other testing as applicable to the device. Test results verify that the device performs per specification requirements and is equivalent to the predicate device without creating additional risk to the patient or user.

Summary of Clinical Testing

No clinical evaluations of this product have been performed.

Statement of Equivalence

Through the data and information presented, Enpath Medical considers the PTFE Peelable Introducer to be remain substantially equivalent to the currently marketed Enpath Medical Percutaneous Introducers based on a comparison of the indications for use and the technological characteristics. The testing performed confirms that the PTFE Peelable Introducer will perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 5 2008

Enpath Medical, Inc.
c/o Ms. Shannon Springer
Principal Regulatory Affairs Associate
2300 Berkshire Lane North
Minneapolis, MN 55441

Re: K081394
Trade/Device Name: PTFE Peelable Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer, Catheter
Regulatory Class: Class II
Product Code: DYB
Dated: August 19, 2008
Received: August 20, 2008

Dear Ms. Springer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality

systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K081394

Device Name: PTFE Peelable Introducer

Indications for Use:

The PTFE Peelable Introducer is intended for use in the percutaneous insertion of pacing leads or catheters in the venous system.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081394